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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,436	12/07/2000	Sudhirdas K. Prayaga	15966-615 (CURA-115)	9940
30623	7590	02/09/2004	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/732,436

Applicant(s)

PRAYAGA ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 42, 43 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 42, 43 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 09, 2003 has been entered.

Response to Amendment

2. Claim 45 has been amended and claim 44 has been cancelled as requested in the amendment of Paper filed on December 09, 2003. Claims 1, 42, 43 and 45 are pending in the instant application.

Claims 1, 42, 43, 45 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on December 09, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

6. Claims 1, 42, 43 and 45 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper No. 26 and section 8 of Paper No. 30. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on premises that there is no “clear preclusion in the statutory language of 35 U.S.C. §101 from submitting after filing evidence to establish utility. Applicants are permitted to submit after filing evidence showing utility as long as there is an appropriate nexus to the subject matter of the specification” (top at page 5 of the Response). This argument has been fully considered but is not deemed persuasive for the following reasons.

Applicant’s attention is directed to the decision of *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which the court expressed the opinion that all chemical compounds are “useful” as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediate obvious or fully disclosed “real world” utility. The court held that:

“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility”, “[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field”, and “a patent is not a hunting license”, “[i]t is not a

reward for the search, but compensation for its successful conclusion”, emphasis added by the Examiner. Thus, based on the decision of *Brenner v. Manson*, utility of the claimed invention must be either fully disclosed or be immediately obvious in currently available form, which precludes any further experimentation to establish the utility of the claimed invention. In the instant case because the instant specification fails to disclosed any “real world” utility for the claimed polypeptide of SEQ ID NO: 6, the instant invention is not complete as filed, and, therefore, clearly lacks utility in currently available form.

Applicant continues to traverse the rejection stating that “SEQ ID NO: 6 is useful in differentiating between pathological and normal brain tissues and cells in Alzheimer’s patients” (first paragraph at page 6 of the Response) and refers to pages 22, 82 and 83 of the instant specification for support of such assertion. These arguments have been fully considered but were not found to be persuasive for the following reasons.

The text on page 22, lines 13-16 reads “Nucleic acids, polypeptides, antibodies, and other compositions of the present invention will be useful in a variety of diseases and pathologies including the treatment of cancer, neurodegenerative disorders, Alzheimer’s Disease, Parkinson’s Disorder, immune disorders, and hematopoietic disorders”. However, the instant specification, as filed, fails to provide any evidence or sound scientific reasoning to support the assertion that the instant polypeptide of SEQ ID NO: 6 is specifically associated with this list of unrelated pathological conditions. Furthermore, the text on page 82, lines 25-29 reads “The levels of gene expression (i.e., a gene expression pattern) can be quantified by Northern blot analysis or RT-PCR, as described herein, or alternatively by measuring the amount of protein produced, by one of the methods as described herein, or by measuring the levels of activity of

NOV or other genes. In this manner, the gene expression pattern can serve as a marker, indicative of the physiological response of the cells to the agent". Thus, the instant passage provides general disclosure of techniques to evaluate gene expression and no information regarding differentially expressed mRNA related to the polypeptide of SEQ ID NO: 6. Finally, the text on page 83, lines 20-28, reads as follows "NOV2 is a member of the transmembrane protein family. Aberrant membrane proteins have been identified in a significant number of diseases, including cancer, neurodegenerative disorders, Alzheimer's Disease, Parkinson's Disorder, immune disorders, and hematopoietic disorders". Again, there appears to be no disclosure of a specific substantial and credible utility at the above noted passage.

Applicant's arguments regarding information in Exhibit A, which was submitted with the previous response to the Office action, were fully answered in section 8 of Paper No. 30. Specifically, because the instant specification, as originally filed, failed to provide any evidence or scientific support that the instant claimed polypeptide of SEQ ID NO: 6 can be used as a marker for Alzheimer's disease, any subsequent data regarding possibility of using the instant polypeptide as a marker for AD is not considered to be persuasive.

Since the instant specification does not disclose a credible "real world" use for the claimed polypeptide then the instant invention is considered to be incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

Claim Rejections - 35 USC § 112

7. Claims 1, 42, 43 and 45 also stand rejected under 35 U.S.C. 112, first paragraph for reasons of record as applied to claims 1-4 in section 6 of Paper No. 26. Specifically, since the

claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

8. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal

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communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.

A handwritten signature in black ink, appearing to read 'Chernyshev', written in a cursive style.